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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/806,828

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Svava Maria Atladottir

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FULWIDER PATTON LLP  
HOWARD HUGHES CENTER  
6060 CENTER DRIVE, TENTH FLOOR  
LOS ANGELES, CA 90045

EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

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04/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/806,828	<b>Applicant(s)</b> ATLADOTTIR ET AL.	
	<b>Examiner</b> ELIZABETH HOUSTON	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15, 38 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 38, 40-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Invention I directed to the apparatus, claims 1-15 and 38-42 in the reply filed on 01/11/08 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1 recites the limitation "the rings of the central section" in line 8; "the rings of the proximal section and distal section" in line 9. There is insufficient antecedent basis for this limitation in the claim. It is unclear whether these limitations refer to the previously recited "plurality of rings" in line 3 or to a different set of rings.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

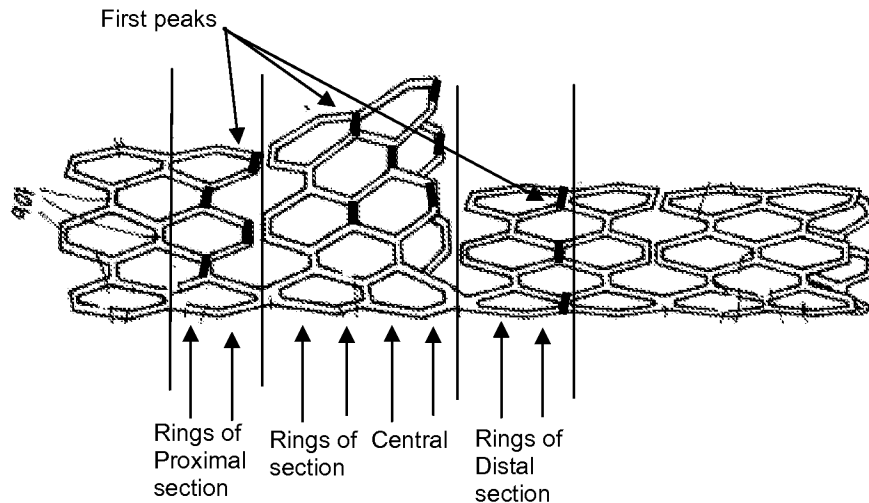
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-10, 15, 38-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Seguin (WO 97/46174).**
6. Seguin discloses a self-expanding stent for treating a bifurcated vessel. The stent has a plurality of rings aligned along a common axis, adjacent rings being connected by

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links (9). The stent has a proximal section, distal section and central section (see below). The number of first peaks (indicated by darkened sections below) in the rings (where a ring is one undulating segment indicated below) of the central section differs from the number of first peaks in the rings of the distal and proximal sections thereby providing additional material for (capable of) apposing a side branch vessel (since the central section is larger and has more first peaks, it inherently has more material capable of apposing the side branch vessel). The first peaks of the rings of the central section are configured to (capable of) flare outward radially into an opening to the side branch vessel (see Figs. 6 and 7). The proximal section has 7 first peaks. (Since the proximal section has at least 7 first peaks including peaks on the other side of the stent that are not shown, it meets the requirement regardless of whether or not there are more than 7 first peaks. The fact that the stent may have additional structure not claimed is irrelevant. Further since the number of first peaks is selectable by the user, exactly 7 first peaks may be chosen.) The distal section has 6 first peaks and the central section has 8 peaks. The number of first peaks in the rings of the central section is greater than the number of first peaks in any of the rings of the proximal or distal sections. The central opening is offset radially from the proximal and distal openings.



### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sequin (US 6,068,655) in view of Guruwaiya (US 6,251,136).**

9. Sequin discloses the invention substantially as claimed except for the layer of drug and the primer material.

10. Guruwaiya discloses a stent coated with a primer layer, which readily adheres to the material of the stent and is in turn constructed to retain a layer of pharmacological agent (Col 2: L20-34). Guruwaiya discloses that it is well known to be beneficial to deliver drugs with stents to treat problems such as thrombosis or neointimal

hyperplasia. Guruwaiya further discloses using a primer layer of a polymer that more readily carries and releases the drugs as a benefit to layering the drug directly to the stent material.

11. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a drug layer into the bifurcated stent since it is an old and well known enhancement to be able to treat the tissue with drugs while at the same time providing the treatment of the stent. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a primer layer between the stent layer and the drug layer since the primer layer will more readily carry and release the drug that the stent material may not be able to carry and release.

**12. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sequin.**

13. As to claim 42, Sequin teaches a bifurcated stent substantially as claimed but is silent as to how the stent is formed. The claimed phrase "formed from a single hypotube" is being treated as a Product by Process limitation. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

(See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

14. Thus, even though, Seguin is silent to the process used to form the stent, it appears that the product disclosed by Seguin would be the same or similar as that claimed; especially since both applicant's product and the prior art product are a bifurcated stent with a middle section that flares into the branch vessel.

### ***Response to Arguments***

15. Applicant's arguments filed 01/11/08 have been fully considered but they are not persuasive. As stated above, the number of first peaks of the central section (identified in the drawing above) is greater than the number of first peaks in the distal or proximal section and therefore it is inherent that the greater number of first peaks in the central section provides additional material that is capable of apposing a side branch vessel.

### ***Conclusion***

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./

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/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731